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(54) **APPARATUS FOR NEGATIVE PRESSURE THERAPY USING WALL SUCTION**

GERÄT FÜR UNTERDRUCKTHERAPIE UNTER VERWENDUNG EINES WAND-
SAUGANSCHLUSSES

APPAREIL POUR THERAPIE PAR ASPIRATION UTILISANT UNE ASPIRATION DE PAROI

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WO-A-96/05873 WO-A-97/18007
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Description

[0001] This invention relates to negative pressure therapy and provides a device which can be used to provide such therapy on connection to an existing source of suction, such as a vacuum line.

[0002] Our prior patent application WO 97/18007 describes portable wound treatment apparatus for stimulating the healing of wounds. The apparatus described in our above application comprises a porous pad, which is permeable to fluids, for packing into or over the wound, dressings for covering and for providing an air-tight seal around the wound, and a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, a canister being provided for collecting fluids which are sucked from the wound.

[0003] The apparatus described in our above application can be worn by the patient on a harness or sling so that he is not confined to one particular place while the therapy is in progress. There is, however, a demand for a more basic piece of equipment which, although not as sophisticated as the equipment described in our above application, does provide some of the benefits of negative pressure therapy.

[0004] Most hospitals have a suction line which is fed to all the wards and is available to nursing staff for a variety of purposes, such as powering drainage tubes and suctioning body fluids generally. For such uses, a pressure regulator may be connected to the source of suction and this regulator may include a pressure gauge indicating the pressure at the regulator valve. It is, however, dangerous to connect such a suction source directly with a patient, without providing continuous supervision. In many hospitals, shortage of staff makes it difficult or impossible to provide adequate close supervision, and if attempts are made to use such a source for negative pressure therapy, there is a very real danger of injuring the patient.

[0005] In some hospitals, vacuum bottles may be employed to assist drainage from wounds, e.g. after operations. Such bottles are containers which are available in various capacities and which are evacuated to low pressure. Vacuum bottles can be used in accordance with the invention as an alternative to a wall suction point. They have the advantage of providing a greater degree of portability to the negative pressure therapy apparatus, but the disadvantage that the bottle needs to be replaced with a fresh bottle once the pressure in the bottle has increased to the vicinity of ambient pressure.

[0006] An object of the present invention is to provide equipment which can be used with an existing wall suction source to safely provide negative therapy to patients.

[0007] According to the invention there is provided an apparatus for applying negative pressure therapy to a wound site, which comprises an open celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, and a pressure

detecting means connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube reaches a predetermined level, characterised in that the apparatus includes a tube for connecting the canister to a wall suction point or to a vacuum bottle, and in that the canister includes a shut-off valve which closes the outlet from the canister when it is full.

[0008] For example, a collection canister of the kind shown in US Patent No. 5,669,892 can be utilised in the first aspect of the invention.

[0009] The apparatus includes a flow limiting valve disposed between the canister and the suction source.

[0010] The apparatus may include a pressure relief valve which is connected to the suction tube between the foam pad and the canister.

[0011] The apparatus may include a first transducer for measuring pressure in the tube linking the canister to the wall suction point or to a vacuum bottle, and a second transducer for measuring pressure at the wound site.

[0012] The apparatus may include flow rate measuring means for measuring the rate at which fluid is sucked from the wound site.

[0013] The flow rate measuring means may comprise a device for measuring the rate at which the canister is filled.

[0014] The flow rate measuring means may be an electrical capacitance measuring device.

[0015] The apparatus may include means for giving a warning that the canister is full and/or shutting off the connection between the canister and the wall suction point.

[0016] The apparatus may further include means for regulating pressure between the canister and the suction source.

[0017] Further features described below may also be introduced into the apparatus as described to give further desirable features.

[0018] Several embodiments in accordance with the invention will now be described with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic representation of one embodiment in accordance with the invention;

Figure 2 is a diagrammatic representation of a second embodiment; and

Figures 3A & 3B are diagrammatic representations of a collection canister for monitoring rates of flow of fluids sucked from the wound.

[0019] Referring to Figure 1 of the drawings, the apparatus for applying negative therapy comprises a foam pad (1) which is applied over or packed into a wound to be treated and is connected by a suction tube (2) to a canister (3). The canister (3) may be of conventional design having a shut-off valve (shown diagrammatically at (140)), which automatically closes once the canister is full. The foam pad may comprise any suitable intercon-

nected cellular foam. Foams which have been found to be especially suitable are polyurethane and polyvinyl alcohol foams or combinations thereof, having interconnected cells.

[0020] As shown in Figures 1 and 2, the foam pad is packed into the open wound and connected to the negative pressure source by a connector device (100) comprising a flexible backing plate (110) and an integral connector tube (120). The connector tube (120) is dimensioned internally to receive the suction tube or tubes (2) as a substantially air-tight fit. The foam pad and connector combination is secured to the wound to be treated by a surgical drape (130), which may be formed with an aperture to permit the tubular part (120) of the connector to pass through the drape.

[0021] A connector of this kind is described in UK Patent Application No. 9819678.5, WO 99/ 13793 and the corresponding US Patent Application filed on 9 July 1999 (attorney ref: 1009.1094) entitled "Surgical drape and suction head for wound treatment".

[0022] A suitable canister of this kind is described in WO 97/18007, European Patent Application Publication No. 0358302 or in US Patent No. 6,142,982 (Application No. 09/078223). The canister is also connected via a further tube (4) to a pressure regulator (5). The pressure regulator carries a gauge (6) and is connected to an existing vacuum line such as a standard hospital wall suction source (97). In many hospital installations a regulator valve (5), together with a pressure gauge (6) already exist, attached to an existing suction source or can be fitted to an existing outlet in the suction source supply. The apparatus may also include an optional flow limiter (8), which may be adjusted to provide different desired levels of flow in the system.

[0023] Pressure in the suction tube (2) is measured by a branch tube (9) which is connected to the suction tube and to a transducer (10). The transducer (10) is mounted on a process control board (12) and this may be connected to a visual display (13). An optional relief valve (11) may also be connected into the tube (9) and provide means for controlling the level of negative pressure at the wound site. The relief valve (11) may be manually settable so that the pressure at the wound site does not exceed a predetermined figure. In view a more esoteric version, the relief valve may be electronically controlled from the PCB to relieve pressure at the wound site at pre-settable maximum pressures. Many hospitals, in addition to having a suction source and a pressure regulator such as regulator (5), also have body fluid collection canisters (3) supplied for other purposes. It may, therefore be possible to supply to the hospital apparatus included in the dotted line shown in Figure 1, together with foams and connecting tubes so that they can connect the existing apparatus to a canister and a regulator (5) available in the hospital.

[0024] A more elaborate system is shown in Figure 2, which is similar to the arrangement shown in Figure 1 except for the following features described below. The

same reference numerals indicate features common to both embodiments. First, the pressure regulator (8) connecting the apparatus to the wall suction source 17 is electronically controlled by the process control board (12). Secondly, the pressure at the wound site is monitored by a transducer (20), while the pressure in the tube connecting the canister to the regulator is measured by a transducer (21). The transducer (20) is connected to the wound side by a tube (23). Instead of providing separate tubes (2) and (23), a single bi- or multi-lumen tube may be used as described in our co-pending application WO97/18007. A relief valve (11) communicates with the tube (23) and enables the apparatus to operate intermittently in a controllable manner by intermittently reducing flow through the regulator (8) and venting pressure through the valve (11). The canister full situation is detected by noting a pressure differential between transducer (20) and transducer (21), or by means of a separate fluid level sensor. Pressure detection at the wound site via the transducer (20) also indicates whether there is a pressure leak or no therapy. A custom-made canister (32) may include means for sensing electronically when the canister is full and must be replaced, e.g. by capacitance measuring means (34). Preferably, the canister is designed to fit into a recess in a custom made housing (30), indicated by dotted lines. The housing may be directly connected at one end to the wall suction point (7), and at the other to a tube or tubes leading to the foam pad (1) at the wound site.

[0025] In the embodiment of Figure 2, the transducers (20 & 21), the relief valve (11) and pressure regulator (8) are preferably all electronically controlled by connections to the PCB. For example, the canister full situation is detected by comparison of the pressure difference between transducers (20 & 21) and this can be signalled on the display (13) and, optionally, also by an audible warning signal.

[0026] It may be desirable to measure the rate at which fluids are sucked from the wound site. This is conveniently achieved by measuring the rate at which the canister is filled with wound exudate. A suitable device is shown diagrammatically in Figure 3. In one configuration shown in Figure 3A, a sleeve (33) is held in intimate contact with the outer surface of the canister. This sleeve carries a single sensing element (35), e.g. capacitive sensor that can provide a means of sensing the presence of liquid at different levels in the canister by simply moving the sleeve up and down the canister. The sensing element detects the presence of liquid by projecting an electrical field into the canister and detecting any change in that field, e.g. by a change in capacitance. The rate of change of capacity over the portion of the canister surveyed by the detector gives an indication of rate of flow of fluid sucked from the wound site.

[0027] In another configuration shown in Figure 3B, a series of sensing elements (36) are evenly spaced on a sleeve (33) that is in contact with the outer surface of the canister. As the fluid level rises within the canister, the

sensing elements are triggered. This information can then be used by the control system at the PCB to deduce flow rate.

Claims

1. Apparatus for applying negative pressure therapy to a wound site, which comprises an open celled foam pad (1) for application to the wound, a suction tube (2) connecting the foam pad (1) to a collection canister (3, 32), a pressure detecting means (10, 20 connected to the suction tube (2) between the foam pad (1) and the canister (3, 32) for indicating when the pressure in the suction tube (2) reaches a predetermined level whereby the apparatus also includes a tube (4) for connecting the canister (3, 32) to a wall suction point (7) or to a vacuum bottle, wherein the canister (3, 32) includes a shut-off valve (140) which closes the outlet from the canister (3, 32) when it is full, and in that the apparatus includes a flow limiting valve (8) disposed between the canister (3, 32) and the suction source (7).
2. Apparatus as claimed in claim 1 which includes a pressure relief valve (11) which is connected to the suction tube (2) between the foam pad (1) and the canister (3, 32).
3. Apparatus as claimed in any one of the preceding claims which includes a first transducer (21) for measuring pressure in the tube (5) linking the canister (3, 32) to the wall suction point (7) or to a vacuum bottle, and a second transducer (20) for measuring pressure at the wound site.
4. Apparatus as claimed in any one of the preceding claims which includes flow rate measuring means (33, 34, 35, 36) for measuring the rate at which fluid is sucked from the wound site.
5. Apparatus as claimed in claim 4 in which the flow rate measuring means (33, 34, 35, 36) comprises a device for measuring the rate at which the canister (32) is filled.
6. Apparatus as claimed in claim 5 in which the flow rate measuring means (33, 34, 35, 36) is an electrical capacitance measuring device.
7. Apparatus according to any preceding claim which includes means for giving a warning that the canister (3, 32) is full and/or shutting off the connection between the canister (3, 32) and the wall suction point (7).
8. Apparatus according to any preceding claim which further includes means (5) for regulating pressure

between the canister (3, 32) and the suction source (7).

5 Patentansprüche

1. Vorrichtung zum Anlegen von Unterdrucktherapie an eine Wundstelle, die ein Kissen (1) aus offenzelligem Schaum zum Anlegen an die Wunde, einen Saugschlauch (2), der das Schaumkissen (1) mit einem Sammelbehälter (3, 32) verbindet, ein Drucknachweisgerät umfasst (10, 20), das mit dem Saugschlauch (2) zwischen dem Schaumkissen (1) und dem Behälter (3, 32) verbunden ist, um anzuzeigen, wenn der Druck im Saugschlauch (2) ein vorbestimmtes Niveau erreicht, wobei die Vorrichtung auch einen Schlauch (4) zum Verbinden des Behälters (3, 32) mit einem Wand-Sauganschluss (7) oder mit einer Vakuumflasche einschließt, wobei der Behälter (3, 32) ein Absperrventil (140) einschließt, das den Auslass aus dem Behälter (3, 32) verschließt, wenn er voll ist, und wobei die Vorrichtung ein Durchflussbegrenzungsventil (8) einschließt, das zwischen dem Behälter (3, 32) und der Saugquelle (7) angeordnet ist.
2. Vorrichtung nach Anspruch 1, die ein Drucktensionsventil (11) einschließt, das mit dem Saugschlauch (2) zwischen dem Schaumkissen (1) und dem Behälter (3, 32) verbunden ist.
3. Vorrichtung nach einem der vorangehenden Ansprüche, das einen ersten Wandler (21) zum Messen des Drucks im Schlauch (5), der den Behälter (3, 32) mit dem Wand-Sauganschluss (7) oder mit einer Vakuumflasche verbindet, und einen zweiten Wandler (20) zum Messen von Druck an der Wundstelle einschließt.
4. Vorrichtung nach einem der vorangehenden Ansprüche, die ein Messgerät für die Durchflussrate (33, 34, 35, 36) zum Messen der Rate, mit der ein Fluid von der Wundstelle abgezogen wird, einschließt.
5. Vorrichtung nach Anspruch 4, wobei das Messgerät für die Durchflussrate (33, 34, 35, 36) eine Einrichtung zum Messen der Rate, mit der der Behälter (32) gefüllt wird, umfasst.
6. Vorrichtung nach Anspruch 5, wobei das Messgerät für die Durchflussrate (33, 34, 35, 36) eine Einrichtung zum Messen der elektrischen Kapazität ist.
7. Vorrichtung nach einem vorangehenden Anspruch, die Mittel zum Abgeben einer Warnung einschließt, dass der Behälter (3, 32) voll ist, und/oder zum Absperrern der Verbindung zwischen dem Behälter

(3,32) und dem Wand-Sauganschluss. (7).

8. Vorrichtung nach einem vorangehenden Anspruch, die weiter Mittel (5) zum Regulieren des Druckes zwischen dem Behälter (3, 32) und der Saugquelle (7) einschließt.

un signal d'alerte que le récipient (3, 32) est plein et/ou pour couper la liaison entre le récipient (3, 32) et le point d'aspiration mural (7).

- 5 8. Appareil selon l'une quelconque des revendications précédentes qui comprend en outre des moyens (5) pour réguler la pression entre le récipient (3, 32) et la source d'aspiration (7).

Revendications

- 10
1. Appareil pour appliquer une thérapie à pression négative à un site de plaie, qui comprend un coussinet de mousse à alvéoles ouverts (1), pour application à une plaie, un tube d'aspiration (2) reliant le coussinet de mousse (1) à un récipient de collecte (3, 15 32), des moyens de détection de pression (10, 20) reliés au tube d'aspiration (2) entre le coussinet de mousse (1) et le récipient (3, 32) pour indiquer quand la pression dans le tube d'aspiration (2) atteint un niveau prédéterminé, moyennant quoi l'appareil 20 comprend également un tube (4) pour relier le récipient (3, 32) à un point d'aspiration mural (7) ou à une bouteille à vide, dans lequel le récipient (3, 32) comprend une vanne d'arrêt (140) qui ferme la sortie du récipient (3, 32) lorsqu'il est plein, et l'appareil 25 comprend une vanne de limitation de débit (8) disposée entre le récipient (3, 32) et la source d'aspiration (7).
2. Appareil selon la revendication 1 qui comprend une 30 vanne de décharge (11) qui est reliée au tube d'aspiration (2) entre le coussinet de mousse (1) et le récipient (3, 32).
3. Appareil selon l'une quelconque des revendications 35 précédentes qui comprend un premier transducteur (21) pour mesurer la pression dans le tube (5) reliant le récipient (3, 32) au point d'aspiration mural (7) ou à une bouteille à vide, et une deuxième transducteur (20) pour mesurer la pression au niveau du site de 40 plaie.
4. Appareil selon l'une quelconque des revendications précédentes qui comprend des moyens de mesure de débit (33, 34, 35, 36) pour mesurer le débit avec 45 lequell un fluide est aspiré du site de plaie.
5. Appareil selon la revendication 4, dans lequel les moyens de mesure de débit (33, 34, 35, 36) comprennent un dispositif pour mesurer le débit auquel 50 le récipient (32) est rempli.
6. Appareil selon la revendication 5, dans lequel les moyens de mesure de débit (33, 34, 35, 36) sont un dispositif de mesure de capacitance électrique. 55
7. Appareil selon l'une quelconque des revendications précédentes qui comprend des moyens pour donner

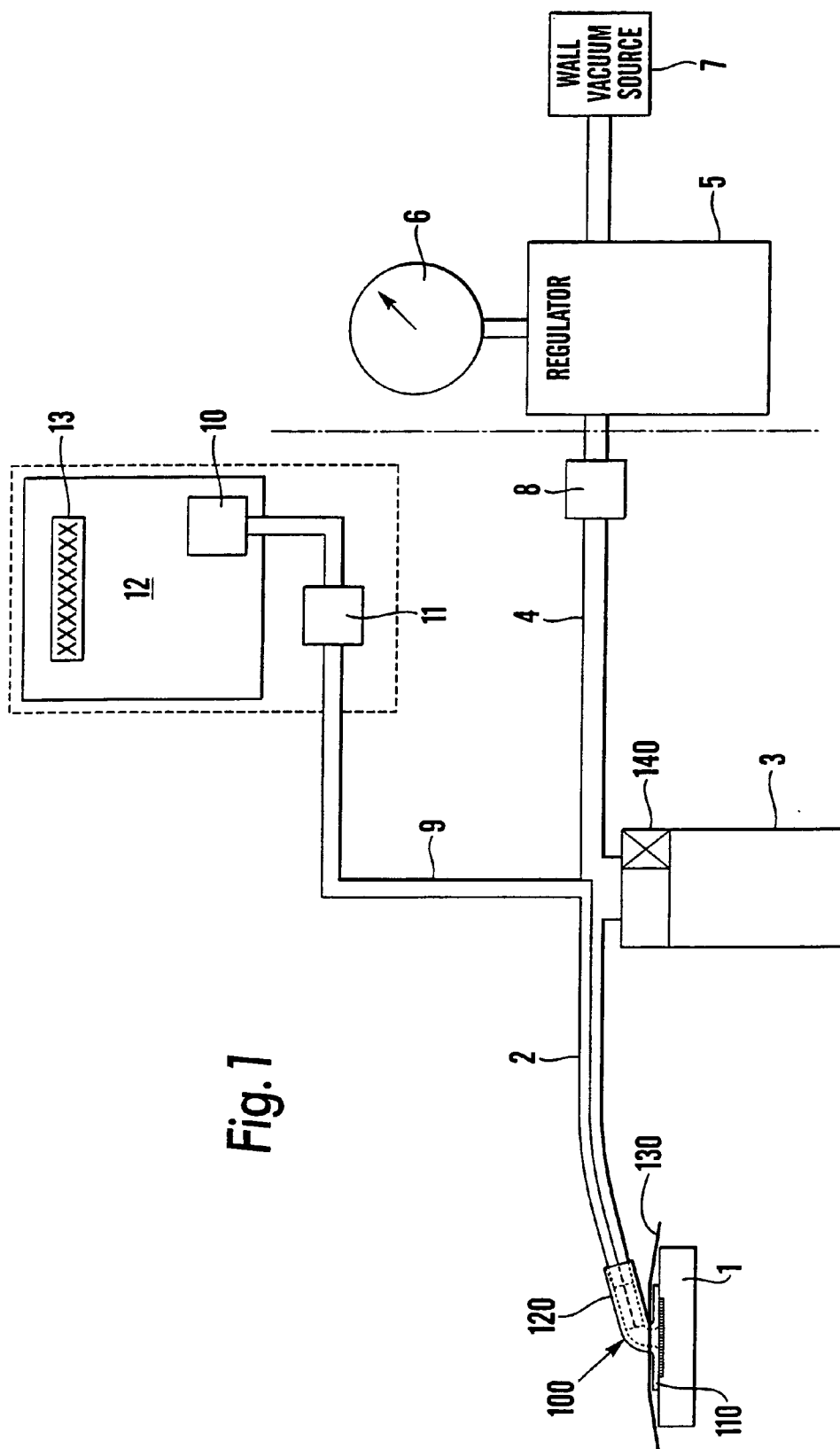
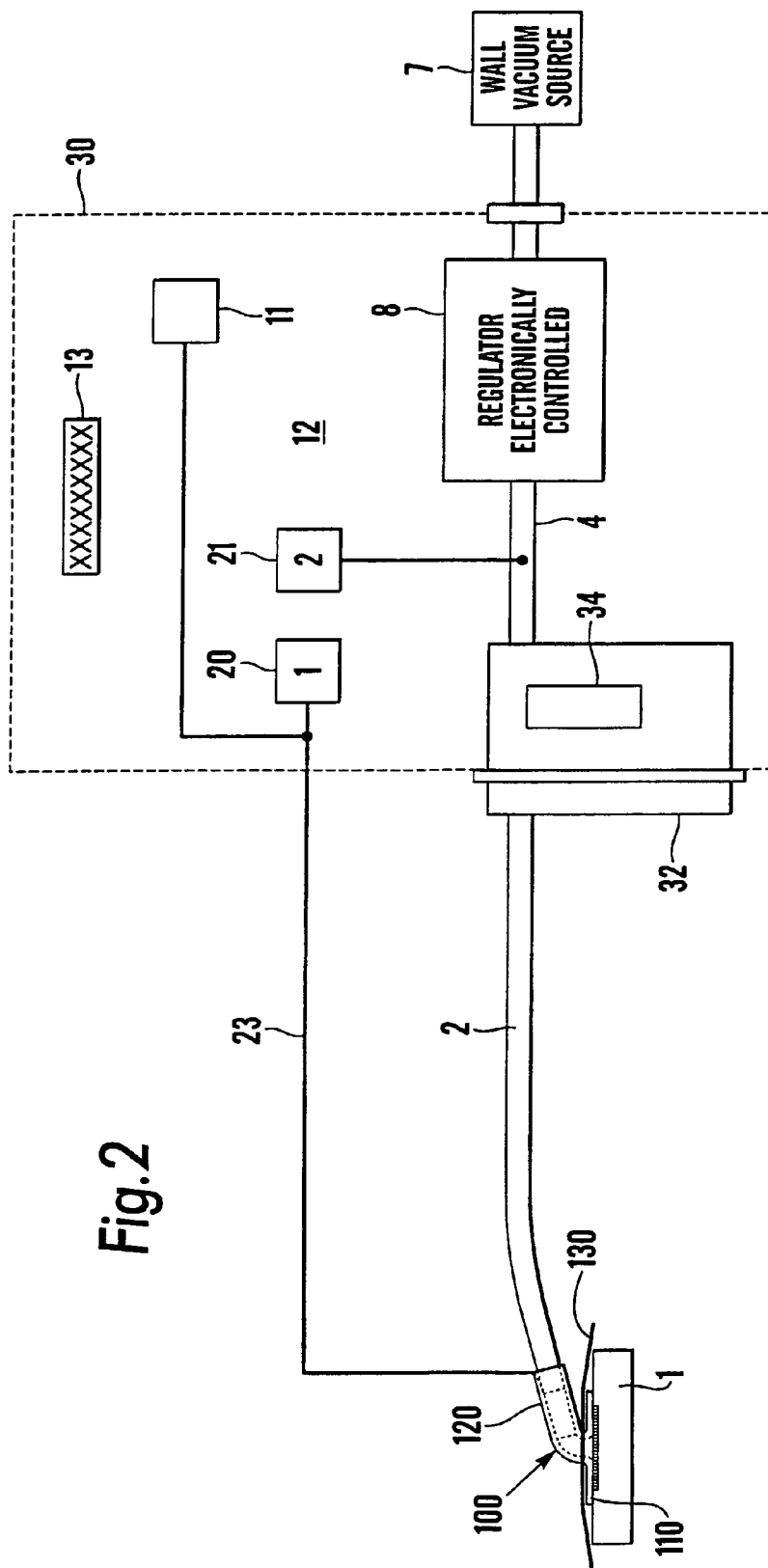


Fig. 1



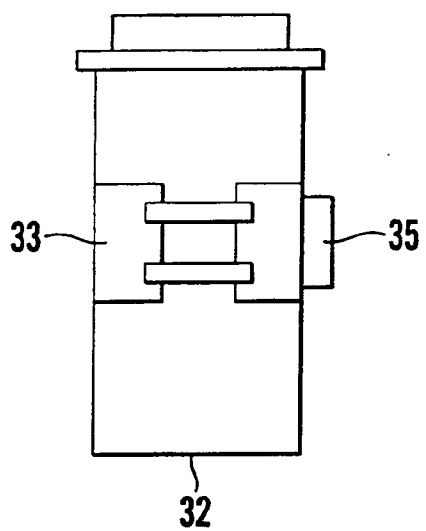


Fig.3A

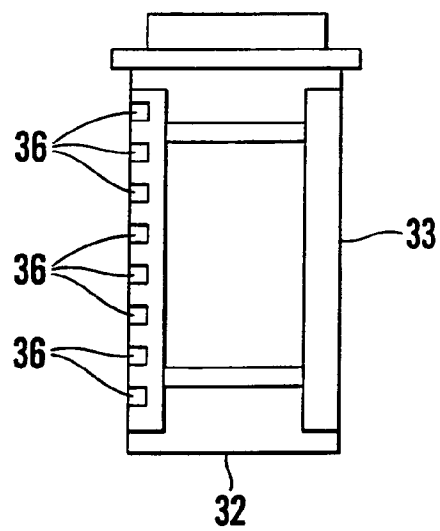


Fig.3B

REFERENCES CITED IN THE DESCRIPTION

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